REMARKS

The present application relates to inbred maize line PH51H. Claims 9, 14, 21, 22, 28, 30 and 47 have been amended. New claims 52-75 have been added. Claims 18-20, 31-33, 36, 43-46 and 48-51 have been canceled. No new matter has been added by the present amendment. Applicant respectfully requests consideration of the following remarks.

Detailed Action

A. Claim and Specification Objections

Applicant acknowledges the rejection of claims 14, 17, 33, 36, 41, 43, 45 and 46 under the judicially created doctrine of obviousness-type double patenting is withdrawn. Applicant further acknowledges the rejection of claims 3, 5, 14, 22, 33, 40-46, 50, and 51 under 35 U.S.C. § 112, second paragraph are withdrawn in light of the previous claim amendments and cancellations. The rejection of claims 18-20 and 47-49 under 35 U.S.C. § 112, first paragraph is also acknowledged by the Applicant as withdrawn.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 22, 30-33, and 47-49 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 22 is indefinite for the recitation "said plant has essentially the same morphology and physiology of inbred maize line PH51H other than the trait of male sterility." The Examiner states it is unclear what is meant by "essentially the same".

Applicant has amended claim 22 to delete the terminology "essentially", thus alleviating this rejection.

The Examiner rejects claim 30 for the recitation "substantially the same" in line 4 as being indefinite.

Applicant has now amended claim 30 to delete the language "substantially", thereby alleviating this rejection.

Claim 33 is indefinite for the recitation "pedigree of said PH51H-progeny maize plant is within 2 or less crosses".

Applicant has now canceled claim 33, alleviating this rejection.

The Examiner rejects claim 47 as indefinite for the recitation "essentially unchanged".

Applicant has amended claim 47 to delete the terminology "essentially", thus alleviating this rejection.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 9-20, 28-39, 41-43, and 47-49 remain rejected and claim 22 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office Action mailed August 26, 2002.

The Applicant traverses the rejection. Claims 18-20, 31-33, 36, 43-46 and 48-51 have been canceled. Claims 9, 14, 28, 30 and 47 have been amended. New claims 52-75 have been added.

The Examiner rejects claims 9, 10, 28, and 29, that claim the F1 hybrid seed and F1 hybrid plant made with PH51H as a parent. Claims 9 and 28 have been amended and claims 10 and 29 refer directly to claims 9 and 28. One of ordinary skill in the art would know how to cross PH51H with another maize plant. Applicants asserts it is well understood by one skilled in the art that maize is a diploid plant species thereby comprising two sets of chromosomes. The F1 hybrid seed and plant produced using PH51H, regardless of the other maize plant used, is identifiable because it will have a single set of individual maize chromosomes coming from PH51H. Therefore, it would be clear to one ordinarily skilled in the art that the addition of claim terminology --having a single set of maize chromosomes from PH51H-- in claims 9 and 28 would certainly be understood. In addition, one of ordinary skill in the art would be able to run a molecular profile on PH51H and the F1 hybrid and be able to identify the F1 hybrid as being

produced from PH51H. Claims 9 and 28 have now been amended to specify that the resulting F1 hybrid must have one set of maize chromosomes from PH51H. PH51H is an inbred plant which is homozygous at every locus, and thus contains two sets of the same chromosomes. When the ovule or pollen are generated from this plant, it will be haploid and will contain one complete set of chromosomes from PH51H. Upon fertilization, the resulting zygote will receive one set of chromosomes from the parent inbred plant resulting in the diploid zygote. Inbred PH51H has a unique set of genes present on its chromosomes and this unique set is also present in the hybrid.

As stated in the specification on page 15, lines 2-29, there are many laboratory-based techniques available for the analysis comparison and characterization of plant genotype such as Restriction Length Polymorphisms (RFLPs) and Simple Sequence Repeats (SSRs). Such techniques may be used to identify whether or not PH51H was used to develop a hybrid. Any person of skill in the art could run a molecular profile of PH51H based upon the deposit Applicant has made. Therefore, it would be routine to one of ordinary skill in the art to run the profile of a hybrid plant and determine whether or not PH51H was used as a parent.

Claims 17 has also been canceled. Claim 14 has been amended providing one of skilled in the art sufficient description to evaluate the presence of the claimed traits. Claims 15 and 16 remain pending and are to methods of making a maize plant through the utilization of PH51H. Applicant points out that anyone of skill in the art would know how to utilize the well established breeding methods with PH51H. Description of such occurs throughout the specification and descriptions can also be found in introductory plant breeding books. As stated in the written description guidelines, an old process performed with a novel material is novel in and of itself. Federal Register, Vol. 66, No. 4 (January 5, 2001).

Claim 43 has been canceled, thereby alleviating the rejection. Claim 40 has been amended. Claim 40 is to the method of producing a first generation (F1) PH51H-progeny maize plant. Claim 41 is to the first generation (F1) PH51H-progeny maize plant produced by the method of claim 40. The first generation (F1), or hybrid, is identifiable through both breeding records and molecular marker techniques as discussed above. Further as described herein, claim 41 requires that the hybrid have the complete set of

PH51H maize chromosomes which are present in duplicate form in the inbred parent. Claim 42 is to the method of selfing the first generation (F1) PH51H for successive filial generations. This is a basic and well known breeding methodology, and the use of this methodology with PH51H is described in the specification on page 20, lines 16 to 31.

As stated in Openshaw et al. submitted herewith, "[t]he backcross breeding procedure has been used widely to transfer simply inherited traits into elite genotypes. ... Today, backcrossing is being used to transfer genes introduced by such techniques as transformation or mutation into appropriate germplasm." Openshaw et al. further notes breeders, by using molecular markers, may obtain 98% and greater genome identity between the backcross conversion and the recurrent parent after two backcrosses. See Marker-assisted Selection in Backcross Breeding, Openshaw, S.J. et al. Marker-assisted selection in backcross breeding. In: Proceedings Symposium of the Analysis of Molecular Data, August 1994, pages 41-43. Crop Science Society of America, Corvallis, OR (1994) included as Appendix A. The backcross method has been successfully used since the 1950's (see pages 585-586 of Wych, 1988 included in the Information Disclosure Statement). Thus Applicant asserts such mutant genes or transgenes may be introgressed into elite lines such as PH51H without undue experimentation. As further evidence of this, Poehlman et al. (1995) on page 334, submitted in the Information Disclosure Statement, states that, "[a] backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross." In addition, Wych (1988) on page 585-86, discusses how the male sterility trait is routinely backcrossed into an inbred line and how this is used to produce a sterile/fertile blend of an F1 hybrid in order to reduce seed production costs. In fact, many commercial products are produced in this manner, and those of ordinary skill in the art consider the F1 hybrid produced with the male sterile (backcross conversion) inbred to be the same variety as the F1 hybrid produced with the non-backcross conversion inbred.

The Examiner states that "the molecular profile of PH51H is not described in the specification." Applicant respectfully traverses this rejection. As described in the specification, lines 2-29 on page 15, the seed deposit allows one of ordinary skill to run a molecular profile of PH51H. Thus, one of ordinary skill in the art may test material they

desire to use in breeding to determine if it is PH51H. An SSR profile is an inherent feature of inbred line PH51H, a representative sample of which has been deposited with the ATCC. For example, see Ex parte Marsili, Rosetti, and Pasqualucci, 214 USPQ 904 (1972), in The Board, relying on well established cases of In re Nathan et al., 51 CCPA 1059, 328 F.2d 1005, 140 USPQ 601 (1964); In re Sulkowski, 487 F.2d 920, 180 USPQ 46 (CCPA 1973); Spero v. Ringold, 54 CCPA 1407, 377 F.2d. 652, 153 USPQ 726 (1967), and Petisi et al. v. Rennhard et al., 53 CCPA 1452, 363 F. 2d 903, 150 USPQ 669 (1966), concluded that the "products described, exemplified and claimed by Appellants inherently had and have now the structure given in the amendment in question". Applicants are willing to provide the molecular marker profile of PH51H.

The Examiner states that, "describing a plant that by saying it expresses 2 particular traits does not distinguish it from any other plant that expresses the same traits." Applicant points out that those claims referenced by the Examiner require the utilization of PH51H to develop such plant. However, in order to expedite prosecution the claims identifying progeny by phenotypic traits have been canceled except for claim 14 which has been amended to clearly claim the parent or grandparent of PH51H expressing all the claimed traits, thereby alleviating the rejection.

The Examiner also states that the morphological and physiological traits of PH51H progeny are not described. The test of written description does not require a morphological and physiological description. Rather, it is whether subject matter was described in such a way to convey to one of ordinary skill in the art that the inventor had possession of the claimed invention. While PVP is distinct from patents, the scope of protection conferred by PVP provides a clear indication that breeders of ordinary skill in the art consider mutations, F1 hybrids, backcross conversions and transgenic conversions to be within the scope of the invention of the variety itself. See Appendix B. These derivatives, variants and closely related progeny easily and routinely created through the use of this newly developed line are encompassed within the scope of the invention of the variety itself. The fact that the progeny have not been created does not prevent them from being protected in this manner. As stated in MPEP § 2163(3)(a), "An invention may be complete and ready for patenting before it has actually been reduced to practice."

The Examiner also rejects claims 37-39 under 35 U.S.C § 112, first paragraph. Claims 37-39 are directed to growing out an F1 hybrid in which PH51H is a parent and searching for PH51H inbred seed. Due to the imperfect process of seed production, parent seed can sometimes be contained in the hybrid seed bag. This claim covers the method of searching for inbred PH51H seed within a bag of hybrid seed. The method is clearly described in the specification on page 5, line 21 through line 7 on page 6. One of ordinary skill in the art can practice such a method without undue experimentation. The Applicant requests that the Examiner withdraw his rejection to claims 37-39.

The Examiner rejects claims to transgenic PH51H plants and PH51H plants comprising single gene conversions. New claims 52-75 are drawn to methods and to the products produced by those methods. The product by process claims are further limited by specified traits conferred by mutant genes or transgenes, which include the traits of insect resistance, herbicide resistance, disease resistance, and male sterility.

Applicant respectfully points out that examples of transgenes, mutant genes, genes, and traits that can be introduced into the PH51H are given in the application on page 20, lines 16-34, and also on page 21, line 34, through page 34, line 25. At the bottom of page 10 of the Office Action the Examiner suggests that the claims be amended to include a list of transgenes. In order to expedite prosecution new claims 52-75 list the type of traits that may be conferred. However it should be noted that PH51H comprising a mutant gene or a transgene, even if it is for a transcription factor, is distinct from another inbred line comprising that same mutant gene or transgene and still retains the benefit of Applicant's invention. Inbred PH51H stably introgressed to comprise a mutant gene or a transgene is also easily identifiable through the use of molecular markers. The transgenic version of PH51H would have the same molecular profile as PH51H, with the possible exception of a marker used in the profile that is located at the site of transgene insertion. However, in this case, the plethora of other identical markers would identify the line as a transgenic variant of PH51H.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections to claims 9-20, 22, 28-39, 41-43, and 47-49 under 35 U.S.C. § 112, first paragraph.

Issues Under 35 U.S.C. § 102/103

Claims 14, 17, 33, 36, 41, and 43 remain rejected and claims 9, 10, 22, 28, 29, and 32 stand rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Piper (U.S. Patent No. 6,188,001). The Examiner asserts this rejection is repeated for the reason of record as set forth in the last Office Action mailed August 26, 2002.

Applicant respectfully traverses this rejection. Applicant has canceled claims 17, 33, 36, and 43, thereby alleviating this rejection. Applicant has amended claim 14 to particularly claim the specific traits to be expressed by the maize plant, thus alleviating this rejection. Further, Applicant has amended claim 41 that is to the first generation (F1) developed from crossing PH51H with a second plant. As explained earlier, the hybrid developed from inbred PH51H as a parent retain the same unique assemblage of genetic material present in duplicate form in the inbred. This contributes predictable traits to the hybrid as described in the specification.

The Examiner states that product-by-process claims may be properly rejected over prior art teaching the same product produced by a different process." It is erroneous to assume that PH1W0 is the same as PH51H either phenotypically or genetically, and Applicant has disclosed information which may be used to distinguish this both from phenotype and genetic profile. PH1W0 is not PH51H, nor can PH1W0 be created through the use of PH51H with one breeding cross. Thus, claim 41 is not anticipated by PH1W0. Further, Applicant submits In re Thorpe, states that "a product by process claim may be properly rejected over prior art teaching the same product produced by a different process", as noted by the Examiner. In re Thorpe, 227 USPQ. 964, 966 (Fed. Cir. 1985). However, Applicant submits that this is not the same product physiologically or morphologically as the cited prior art as can be evidenced by one skilled in the art through analysis of the data tables in each. In addition, it is impermissible to use hindsight reconstruction and the benefit of Applicant's disclosure to pick among pieces which are present in the art, there must be some suggestion to make the combination and an expectation of success. In re Vaeck, 20 USPQ2d 1434 (Fed. Cir. 1991). Moreover, Applicant claims a method of making a plant which did not previously exist. Pursuant to the recent Federal Circuit decision, Elan Pharmaceuticals, Inc. v. Mayo Foundation for

Medical Education & Research, 304 F.3d 1221, (Fed. Cir. 2002), "a novel patented product is not "anticipated" if it did not previously exist." Id. This is the case whether or not the process for making the new product is generally known. Id. The invention PH51H has not previously existed therefore Applicants strongly assert that neither the suggestion of the claimed unique invention of the present application nor the expectation of success is taught for one ordinarily skilled in the art in the reference cited by the Examiner.

In light of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections to under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Piper (U.S. Patent No. 6,188,001).

Summary

Applicant acknowledges that claims 1-8, 21, 23-27, and 40 are allowed.

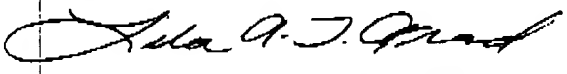
Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested.

No additional fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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Marker-assisted Selection in Backcross Breeding

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Abstract. **The backcross breeding procedure has been used widely to transfer simply inherited traits into elite genotypes. Genetic markers can increase the effectiveness of backcrossing by 1) increasing the probability of obtaining a suitable conversion, and 2) decreasing the time required to achieve an acceptable recovery. Simulation and field results indicated that, for a genome consisting of ten 200-cM chromosomes, basing selection on 40 or 80 markers in 50 BC individuals that carry the allele being transferred can reduce the number of backcross generations needed from about seven to three.**

The backcross breeding procedure has been used widely to transfer simply inherited traits into elite genotypes. Usually, the trait being transferred is controlled by a single gene, but highly heritable traits that are more complexly inherited have also been transferred successfully by backcrossing; for example, maturity in maize (Rinke and Sentz, 1961; Shaver, 1976). Today, backcrossing is being used to transfer genes introduced by such techniques as transformation or mutation into appropriate germplasm.

Several plant breeding textbooks give good descriptions of the backcross procedure (Allard, 1960; Fehr, 1987). A donor parent (DP) carrying a trait of interest is crossed to the recurrent parent (RP), an elite line that is lacking the trait. The F_1 is crossed back to the RP to produce the BC_1 generation. In the BC_1 and subsequent backcross generations, selected individuals carrying the gene being transferred are backcrossed to the RP. The expected proportion of DP genome is reduced by half with each generation of backcrossing. Ignoring effects of linkage to the selected DP allele being transferred, the percentage recurrent parent (%RP) genome expected in each backcross generation is calculated as:

$$\%RP = 100\,[1 - (0.5)^{n+1}]$$

where n is the number of backcrosses.

Backcrossing of selected plants to the RP can be repeated each cycle until a line is obtained that is essentially a version of the RP that includes the introgressed allele. After six backcrosses, the expected recovery is >99% (Table 1).

Until recently, discussions of the recovery of the RP genome during backcrossing have emphasized the expected values for %RP shown in Table 1, and have largely ignored the genetic variation for %RP that exists around the expected mean. With the development of genetic markers capable of providing good genome coverage, there has been interest in taking advantage of that variation to increase the efficiency of backcrossing.

Selection for RP marker alleles can increase greatly the effectiveness of backcross programs by allowing the breeder to 1) select backcross plants that have a higher proportion of RP genome, and 2) select backcross individuals that are better conversions near a mapped donor allele being transferred (i.e., select for less linkage drag). Expressed in practical terms, using genetic markers to assist backcrossing can 1) increase the probability of obtaining a suitable conversion, and 2) decrease the time required to achieve an acceptable recovery.

Issues to consider when planning a marker-assisted backcross program include 1) the time advantage of using markers to assist backcrossing, 2) the number of markers needed, and 3) the number of genotypes to evaluate. In this report, we use results from previous literature, computer simulation, and empirical studies to provide some guidelines.

Table 1. Expected recovery of recurrent parent (RP) genome during backcrossing, assuming no linkage to the gene being transferred.

Generation	%RP
F_1	50.0000
BC_1	75.0000
BC_2	87.5000
BC_3	93.7500
BC_4	96.8750
BC_5	98.4375
BC_6	99.2188
BC_7	99.6094

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Materials and methods

The maize genome was the model for the simulation. The simulated genome contained ten 200-cM chromosomes. Simulation of crossing over was based on a Poisson distribution with a mean of 2.0 ($\lambda = 2$) (Hanson, 1959), which, on average, generated one cross over for every 100-cM length. The simulations reported here assume no interference. Codominant genetic markers were evenly distributed in the genome and sites of the donor gene were randomly assigned to genome locations.

Simulations were conducted with the following parameters:

Number of progeny: 100 or 500.
Backcross generations: BC_1, BC_2, and BC_3.
Number of markers: 20, 40, 80, or 100.
Number selected to form the next BC generation: 1 or 5.

Selection was based on 1) presence of the donor allele and 2) high %RP). %RP was calculated as the average of the (one or five) selected individuals. Values presented are the mean of 50 simulations.

Results

In the computer simulation study, all methods modeled greatly increased the speed of recovering the RP genome compared to the expected recovery with no marker-assisted selection (compare Tables 1 and 2). At least 80 markers were required to recover 99% of the RP genome in just three BC generations (Table 2). Use of at least 80 markers and 500 progeny allowed recovery of 98% RP in just two BC generations. Response to selection was diminished only slightly by spreading the effort over five selections. Using markers, the number of backcross generations needed to convert an inbred is reduced from about seven to three.

By the BC_2 generation, there appears to be no practical advantage to using 500 vs. 100 individuals. If the presence of the donor trait in the backcross individuals can be ascertained before markers are genotyped, then only half the number of individuals indicated in the tables will need to be analyzed.

When a small number of markers are used, they quickly became non-informative; i.e., selection causes the marker loci to became fixed for the RP type before the rest of the genome is fully converted (Table 3; Hospital et al., 1992). This situation was most prominent in the larger populations, where a higher selection intensity placed more selection pressure upon the marker loci. Accordingly, it is of interest to consider how closely the estimation of %RP based on markers reflects the actual genome composition. The combination of estimation of %RP based on fewer markers and subsequent selection tends to bias the estimates upward (compare Tables 2 and 3).

The results from the simulation compare well with real field data. In a typical example, 50 BC_1 plants carrying the gene being transferred were genotyped at 83 polymorphic RFLP loci (note that this corresponds to a population size of 100 unselected plants in Tables 2 and 3). The five best BC_1 recoveries had estimated %RP values of 85.9%, 82.7%, 82.0%, 81.4%, and 81.2%. After evaluating 10 BC_2 plants from each selected BC_1, the best BC_2 recovery had an estimated %RP of 94.6%.

Discussion

The simulations (Table 2; Hospital et al., 1992) and our experience indicate that four markers per 200-cM chromosome is adequate to greatly increase the effectiveness of selection in the BC_1. However, using only four markers per 200 cM will likely make it very difficult to map the location of the gene of interest. Adequate summarization of the data is an important

Table 2. *Percent recurrent parent genome during marker-assisted backcrossing.*

	100 Progeny				500 Progeny			
	No. markers				No. markers			
Generation	20	40	80	100	20	40	80	100
				One selected				
BC_1	84.5	84.5	84.2	88.0	89.9	90.7	90.2	90.5
BC_2	95.0	95.2	95.8	97.2	96.5	97.7	98.5	98.6
BC_3	97.4	97.6	98.9	99.2	97.7	98.3	99.4	99.5
				Five selected				
BC_1	82.9	85.1	84.9	84.7	87.7	88.1	88.9	88.9
BC_2	93.7	95.0	95.8	95.7	95.5	96.8	97.8	97.9
BC_3	97.1	98.3	98.8	98.9	97.3	98.5	99.3	99.3

Table 3. *Estimates of percent recurrent parent genome, based on marker loci.*

	100 Progeny				500 Progeny			
	No. markers				No. markers			
Generation	20	40	80	100	20	40	80	100
				One selected				
BC_2	98.7	97.8	95.6	97.2	100.0	99.1	98.6	98.0
BC_3	100.0	99.8	99.3	99.5	100.0	100.0	99.9	98.2
				Five selected				
BC_2	96.4	96.5	96.2	95.8	100.0	98.5	98.3	98.2
BC_3	99.9	99.8	99.3	99.1	100.0	100.0	99.9	99.8

part of a marker-assisted backcross program. Ideally, the markers used can supply data that can be represented as alleles of loci with known map position. Estimation of %RP, mapping the position of the locus of interest, and graphical display of the results (Young and Tanksley, 1989) are all useful in understanding and controlling the specific backcross experiment being conducted.

It appears that, with the use of genetic markers, the portion of the RP genome that is not linked to the allele being transferred can be recovered quickly and with confidence. The recovery of RP will be slower on the chromosome carrying the gene of interest. A considerable amount of linkage drag is expected to accompany selection for the DP allele in a backcross program. For a locus located in the middle of a 200-cM chromosome, the length of the DP chromosome segment accompanying selection is expected to be 126, 63, and 28 cM in the BC_1, BC_2, and BC_3 generations, respectively (Hanson, 1959; Naveira and Barbadilla, 1992). Our observations support the recommendation of Hospital et al. (1992) that preference be given to the selection for recombinants proximal to the allele of interest, but that selection for recovery of the RP elsewhere in the genome also be considered. This two-stage selection can probably be done quite effectively ad hoc by the breeder once the data is adequately summarized; however, Hospital et al. suggest ways to incorporate the two criteria into a selection index such that each component of selection is assured appropriate weighting.

Use of genetic markers can greatly increase the effectiveness of backcrossing, and they should be used in any serious backcrossing program if resources are available to the breeder.

Literature Cited

Allard, R.W. 1960. Principles of plant breeding. Wiley, New York.

Fehr, W.R. 1987. Principles of cultivar development: v.1. Theory and technique. Macmillan, New York.

Hanson, W.D. 1959. Early generation analysis of length of heterozygous chromosome segments around a locus held heterozygous with backcrossing or selfing. Genetics 44:843–847.

Hospital, F., C. Chevalet, and P. Mulsant. 1992. Using markers in gene introgression breeding programs. Genetics 132:1199–1210.

Rinke, E.H and J.C. Sanz. 1961. Moving corn-belt germplasm northward. Ann. Hybrid Corn Industry Conf. 16:53–56.

Shaver, D.L. 1976. Conversions for earliness in maize inbreds. Maize Genet. Coop. Newsltr. 50:20–23.

Young, N.D. and S.D. Tanksley. 1989. Restriction fragment length polymorphism maps and the concept of graphical genotypes. Theo. Applied Genet. 77: 95–101.

Essentially Derived Variety

What is an "Essentially Derived Variety"?

The concept of essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-crossing and to fill the gap between Plant Breeder's Rights and patents, gap which was becoming important due to the development of the use of patented genetic traits in genetic engineering.

An essentially derived variety is a variety which is distinct and predominantly derived from a protected initial variety, while retaining the essential characteristics of that initial variety.

As indicated as an example in the UPOV Convention, essentially derived varieties may be obtained by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, back-crossing, or transformation by genetic engineering.

The commercialization of an essentially derived variety needs the authorization of the owner of the rights vested in the initial variety.

The concept of essentially derived variety does not at all abolish the Breeder's Exemption, as free access to protected plant varieties for breeding purposes is maintained. It is not a threat to biodiversity. On the contrary, it favors biodiversity, encouraging breeders developing and marketing original varieties.

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INTERNATIONAL CONVENTION

FOR THE

PROTECTION OF NEW VARIETIES OF PLANTS

of December 2, 1961, as revised
at Geneva on November 10, 1972,
on October 23, 1978, and
on March 19, 1991

adopted by the Diplomatic Conference

on March 19, 1991

reproduced from UPOV Publication No. 438(E)

issue No. 63 of "Plant Variety Protection"

1991 Act of the Convention

Article 12
Examination of the Application

Any decision to grant a breeder's right shall require an examination for compliance with the conditions under Articles 5 to 9. In the course of the examination, the authority may grow the variety or carry out other necessary tests, cause the growing of the variety or the carrying out of other necessary tests, or take into account the results of growing tests or other trials which have already been carried out. For the purposes of examination, the authority may require the breeder to furnish all the necessary information, documents or material.

Article 13
Provisional Protection

Each Contracting Party shall provide measures designed to safeguard the interests of the breeder during the period between the filing or the publication of the application for the grant of a breeder's right and the grant of that right. Such measures shall have the effect that the holder of a breeder's right shall at least be entitled to equitable remuneration from any person who, during the said period, has carried out acts which, once the right is granted, require the breeder's authorization as provided in Article 14. A Contracting Party may provide that the said measures shall only take effect in relation to persons whom the breeder has notified of the filing of the application.

CHAPTER V
THE RIGHTS OF THE BREEDER

Article 14
Scope of the Breeder's Right

(1) [Acts in respect of the propagating material] (a) Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:

(i) production or reproduction (multiplication),

(ii) conditioning for the purpose of propagation,

(iii) offering for sale,

(iv) selling or other marketing,

(v) exporting,

(vi) importing,

(vii) stocking for any of the purposes mentioned in (i) to (vi), above.

(b) The breeder may make his authorization subject to conditions and limitations.

(2) [Acts in respect of the harvested material] Subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating material of the protected variety shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material.

(3) [Acts in respect of certain products] Each Contracting Party may provide that, subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of products made directly from harvested material of the protected variety falling within the provisions of paragraph (2) through the unauthorized use of the said harvested material shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said harvested material.

(4) [Possible additional acts] Each Contracting Party may provide that, subject to Articles 15 and 16, acts other than those referred to in items (i) to (vii) of paragraph (1)(a) shall also require the authorization of the breeder.

(5) [Essentially derived and certain other varieties] (a) The provisions of paragraphs (1) to (4) shall also apply in relation to

(i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,

(ii) varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety and

(iii) varieties whose production requires the repeated use of the protected variety.

(b) For the purposes of subparagraph (a)(i), a variety shall be deemed to be essentially derived from another variety ("the initial variety") when

(i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,

(ii) it is clearly distinguishable from the initial variety and

(iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

(c) Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

Article 15
Exceptions to the Breeder's Right

(1) [Compulsory exceptions] The breeder's right shall not extend to

(i) acts done privately and for non-commercial purposes,

(ii) acts done for experimental purposes and

(iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties.

(2) [Optional exception] Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting,